May 13, 2004

Michael O. Leavitt, Administrator U.S. Environmental Protection Agency Ariel Rios Building, 1101-A 1200 Pennsylvania Ave., N.W. Washington, DC 20460

Subject: Comments on the HPV Test Plan for Phenol, heptyl derivatives

Dear Administrator Leavitt:

The following comments on ACC's HERTG test plan for the chemical Phenol, heptyl derivatives are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

The American Chemistry Council Petroleum Additives Panel Health, Environmental, and Regulatory Task Group (HERTG) submitted its test plan on January 14, 2004, for the chemical Phenol, heptyl derivatives (CAS No. 72624-02-3), also referred to as *p*-heptylphenol. This chemical is used to manufacture lubricant additives which are further processed for use in industrial and automotive gear oils, automatic transmission formulations, and small engine applications. In its test plan, HERTG proposes to conduct a combined repeated dose/reproduction/developmental screen, OEDC 422, among other tests, claiming that no existing data are available to meet certain SIDS endpoints. If the combined study is conducted, at least 675 animals will be killed.

We strenuously object to HERTG's proposal to conduct OECD 422 for this chemical. This exact same compound is already sponsored in the HPV program by Schenectady International, Inc. The test plan for the Alkylphenols category was submitted by Schenectady in May 2001. Revisions to the original test plan were submitted in April 2003, with no new mammalian toxicity testing proposed for any of the members of the category, including p-heptylphenol. It is extremely alarming that HERTG chose not to coordinate their test plan with that of Schenetady.

The sponsored chemical in the current test plan by HERTG, *p*-heptylphenol, is a parasubstituted mono-alkylphenol and can be grouped with three similar chemicals that have **existing repeated dose/reproductive/developmental data available**: *p-tert*-butylphenol (CAS No. 98-54-4), *p-tert*-octylphenol (CAS No. 140-66-9), and *p*-nonylphenol (CAS No. 84852-15-3). Although there are no available data on repeated dose, reproduction,

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and developmental toxicity of *p*-heptylphenol *per se*, all of these endpoints are filled using data from analogous chemicals (mentioned above) in Schenetady's test plan for the Alkylphenol category. HERTG's test plan for *p*-heptylphenol is a clear violation of the October 1999 agreement letter which directs HPV participants to coordinate test plans with one another. This letter states "participants shall maximize the use of scientifically appropriate categories of related chemicals" and asks sponsors to "maximize the use of existing and scientifically adequate data to minimize further testing."

We are dismayed that HERTG has proposed to kill 675 animals in a combined repeated dose/reproductive/developmental toxicity study which is redundant and completely unnecessary. We strongly urge the EPA to reject HERTG's proposal to conduct OECD 422 and to require collaboration between HERTG and Schnectady for data collection on *p*-heptylphenol.

Thank you for your attention to these comments. I look forward to a prompt and favorable response to our concerns. I may be reached at 202-686-2210, ext. 327, or via e-mail at *meven@pcrm.org*.

Sincerely,

Megha Even, M.S. Research Analyst

Chad B. Sandusky, Ph.D. Director of Research